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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,798	02/27/2004	Timothy R. H. Pratt	300569	9447

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FAEGRE & BENSON LLP
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EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
05/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/789,798	PRATT ET AL.	
	Examiner	Art Unit	
	LENA NAJARIAN	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *1-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060426; 20080208; 20090216*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 39-51 in the reply filed on 4/20/09 is acknowledged.

2. Claims 1-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/20/09.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 39-51 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

5. Claims 39-51 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Under the statute, the claimed invention must fall into one of the four recognized statutory classes of invention, namely, a process (or method); a machine (or system); an article of manufacture; or a composition of matter.

In the present case, claim 39, for example, only recites mental steps. In order to qualify as a statutory process, the claim should positively recite the other statutory class

(the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state. The recited steps of claim 39 of merely receiving a data set, analyzing the data set, and determining whether an implantable medical device's parameters are configured properly are not tied to another statutory class (such as a particular apparatus) and do not transform underlying subject matter (such as an article or materials) to a different state or thing. Therefore, claims 39-51 are deemed to be directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Bardy (US 2002/0022776 A1).

(A) Referring to claim 39, Bardy discloses a method for automatically validating medical data received via a communication network, comprising (abstract of Bardy):

receiving a data set from an implantable medical device (para. 13 of Bardy);

analyzing the data set from the implantable medical device to determine implantable medical device configuration parameters (para. 11, 13, and 43 of Bardy); and

determining whether the implantable medical device configuration parameters are configured properly (para. 44, Fig. 11, and para. 62 of Bardy).

(B) Referring to claim 40, Bardy discloses notifying a physician to reconfigure the implantable medical device if it is configured improperly (para. 44 of Bardy).

(C) Referring to claim 41, Bardy discloses wherein the physician is notified to reconfigure the implantable medical device electronically (para. 44 of Bardy).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0022776 A1) in view of Krichen et al. (6,250,309).

(A) Referring to claims 42 and 43, Bardy does not disclose wherein the data set from the implantable medical device is received in a first data format, and wherein the method further comprises: converting the data set from the first data format to a second

data format; and validating the second data format against the first data format to verify that the conversion from the first data format to the second data format occurred without errors and wherein the first data format comprises a binary data format, and the second data format comprises an extensible mark-up language (XML) data format.

Krichen discloses wherein the data set from the implantable medical device is received in a first data format, and wherein the method further comprises: converting the data set from the first data format to a second data format (col. 2, lines 52-61 of Krichen); and validating the second data format against the first data format to verify that the conversion from the first data format to the second data format occurred without errors (col. 2, lines 31-61 and col. 13, lines 27-43 of Krichen) and wherein the first data format comprises a binary data format, and the second data format comprises an extensible mark-up language (XML) data format (col. 2, lines 52-61 of Krichen).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Krichen within Bardy. The motivation for doing so would have been to provide a format that can be manipulated at a remote location (col. 2, lines 31-36 of Krichen).

8. Claims 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0022776 A1) in view of Boone et al. (US 2004/0243545 A1).
(A) Referring to claim 44, Bardy does not disclose receiving a data set comprising patient information entered by a physician; validating at least a portion of the patient

information data set against validation parameters to determine if the entered patient information contains errors; prompting the physician to correct one or more errors if one or more errors exist, wherein after the one or more errors are corrected, the patient information is validated; and storing the validated patient information.

Boone discloses receiving a data set comprising patient information entered by a physician (para. 45 of Boone); validating at least a portion of the patient information data set against validation parameters to determine if the entered patient information contains errors (para. 46-48 of Boone); prompting the physician to correct one or more errors if one or more errors exist, wherein after the one or more errors are corrected, the patient information is validated (para. 46-48 of Boone); and storing the validated patient information (para. 48 of Boone).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Boone within Bardy. The motivation for doing so would have been to verify the information and provide a database with accurate information (para. 48 of Boone).

(B) Referring to claim 45, Bardy does not disclose wherein the patient information is validated during a patient data entry session.

Boone discloses wherein the patient information is validated during a patient data entry session (abstract and para. 28 of Boone).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Boone within Bardy. The

motivation for doing so would have been to make corrections consistently (abstract and para. 28 of Boone).

(C) Referring to claim 46, Bardy discloses wherein the patient information is selected from the group consisting of objective patient information, subjective patient information, and patient diagnosis information (para. 63 of Bardy).

(D) Referring to claim 47, Bardy does not disclose wherein the patient information data set comprises data associated with one or more fields, and wherein the validation parameters comprise validation rules for the one or more fields.

Boone discloses wherein the patient information data set comprises data associated with one or more fields, and wherein the validation parameters comprise validation rules for the one or more fields (para. 71-72 of Boone).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Boone within Bardy. The motivation for doing so would have been to provide a standard format (para. 72 of Boone).

(E) Referring to claim 48, Bardy does not disclose receiving a data set comprising patient information entered by a physician; validating at least a portion of the patient information data set against patient information previously stored in a database to determine if any portion of the entered patient information is inconsistent with the stored patient information; and prompting the physician to verify that the entered patient

information is accurate and correct any entered patient information that is determined to not be accurate if inconsistencies are located.

Boone discloses receiving a data set comprising patient information entered by a physician (para. 45 of Boone); validating at least a portion of the patient information data set against patient information previously stored in a database to determine if any portion of the entered patient information is inconsistent with the stored patient information (para. 46-48 of Boone); and prompting the physician to verify that the entered patient information is accurate and correct any entered patient information that is determined to not be accurate if inconsistencies are located (para. 29 and para. 46-48 of Boone).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Boone within Bardy. The motivation for doing so would have been to verify the information and provide a database with accurate information (para. 48 of Boone).

9. Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0022776 A1) in view of Boone et al. (US 2004/0243545 A1), and further in view of Sullivan (US 2002/0077865 A1).

(A) Referring to claim 49, Bardy and Boone do not disclose wherein the patient information data set comprises data associated with a plurality of fields, the plurality of

fields including a first field to receive a first measurement value for a patient symptom test and a second field to receive a second measurement value for the patient symptom test, and wherein the method further comprises: validating that the second field includes the second measurement value; and prompting the physician to enter the second measurement value into the second field if the second field does not include the second measurement value.

Sullivan discloses wherein the patient information data set comprises data associated with a plurality of fields, the plurality of fields including a first field to receive a first measurement value for a patient symptom test and a second field to receive a second measurement value for the patient symptom test, and wherein the method further comprises: validating that the second field includes the second measurement value; and prompting the physician to enter the second measurement value into the second field if the second field does not include the second measurement value (Fig. 2, Fig. 17, para. 29, and para. 129 of Sullivan).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Sullivan within Bardy and Boone. The motivation for doing so would have been to include the important or critical elements of documentation of a patient's particular medical condition in the medical record (para. 29 of Sullivan).

(B) Referring to claim 50, Bardy and Boone do not disclose validating the second field against the first field to determine if the second measurement value is reasonable in

view of the first measurement value; and if the second measurement value is not reasonable in view of the first measurement value, prompting the physician to verify the first measurement value, verify the second measurement value, enter a new first measurement value, or enter a new second measurement value.

Sullivan discloses validating the second field against the first field to determine if the second measurement value is reasonable in view of the first measurement value; and if the second measurement value is not reasonable in view of the first measurement value, prompting the physician to verify the first measurement value, verify the second measurement value, enter a new first measurement value, or enter a new second measurement value (para. 99, para. 121, para. 128, and para. 131 of Sullivan).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Sullivan within Bardy and Boone. The motivation for doing so would have been so that the symptoms presented by the patient are properly and quickly evaluated and documented (para. 99 of Sullivan).

10. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0022776 A1) in view of Joyce et al. (US 2001/0053984 A1).
(A) Referring to claim 51, Bardy does not disclose receiving a data set comprising subjective patient information entered by a physician; and normalizing the subjective information to adjust for physician biases.

Joyce discloses receiving a data set comprising subjective patient information entered by a physician; and normalizing the subjective information to adjust for physician biases (para. 5, para. 44, para. 49-52 of Joyce).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Joyce within Bardy. The motivation for doing so would have been to assess treatment protocols (para. 7 of Joyce).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a system of implantable devices for monitoring and/or affecting body parameters (US 6,208,894 B1); an automated data integrity auditing system (US 6,542,905 B1); and a microprocessor controlled ambulatory medical apparatus with hand held communication device (US 2002/0016568 A1).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571) 272-7072. The examiner can normally be reached on Monday - Friday, 9:30 - 6:00.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/L. N./
Examiner, Art Unit 3686
ln
5/11/09

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686